510(K) SUMMARY K062479

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

MAR 14 2007

1. Submitter's Name: **JOYKEY INDUSTRYIAL LTD.**
   Address: Unit 7-8,23rd Floor, No. 1, Hung To Road, Kwun Tong, KL , Hong Kong
   Phone: 852-2612-0951
   Fax: 852-2615-9138
   Contact: Ms. Ting-Yu Chang (President)

2. Device Name
   Trade Name: **JOYKEY Surgical Gowns(Sterile)**
   Common Name: Sterile Surgical Gowns
   Classification name: GOWN , SURGICAL

3. Classification: Class II

4. Predicate Device: **Master & Frank Surgical Gowns (Sterile) (K012186)** marketed by Master & Frank Enterprise Co., Ltd.

5. Device Description: JOYKEY Surgical Gowns (Sterile) are non-reinforced surgical Gowns manufactured from non-woven fabric. The surgical Gown is supplied sterile and for single use only.

6. Intended Use: **JOYKEY Surgical Gowns (Sterile)** are single use article of surgical apparel worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

K062479

7. Performance Summary: In terms of Physical specification, The device conforms to ASTM F1670-03 Barrier properties against blood and body fluids & ASTM D1424 , ASTM D5034 & NFPA Flammability standards----etc. The device also conforms to Biological standards of ISO 10993 series, Gamma Sterilization standard of ISO 11137.

8. Conclusions:

The **JOYKEY Surgical Gowns (Sterile)** have identical intended use and technological characteristics as the **Master & Frank Surgical Gowns (Sterile) (K012186).** Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **JOYKEY Surgical Gowns (Sterile)** are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Joykey Industryial, Limited
C/O Ms. Jennifer Reich
2904 North Boldt Drive
Flagstaff, Arizona 86001

MAR 14 2007

Re: K062479
Trade/Device Name: JOYKEY Surgical Gowns (Sterile)
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: February 15, 2007
Received: February 20, 2007

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062479

Device Name: **JOYKEY Surgical Gowns (Sterile)**
JOYKEY INDUSTRYIAL LTD.

Indications For Use:

JOYKEY Surgical Gowns (Sterile) are single use article of surgical apparel worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Prescription Use _____ AND/OR Over-The-Counter Use V
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A. Murphy MS

K062479